SECTION THREE: TEXAS DEPARTMENT OF HEALTH AND PROVIDER RESPONSIBILITIES

RESPONSIBILITIES

The Texas Department of Health (TDH) is responsible for assuring that the goals and objectives of the Breast and Cervical Cancer Control Program (BCCCP) are met and funds are appropriately expended. TDH contracts and collaborates with agencies and organizations throughout the sate to accomplish the BCCCP objectives.

I. QUALITY ASSURANCE

A. Program Monitoring

Program providers and the TDH must collaborate closely to attain performance requirements and quality indicators to comply with federal law and guidelines of the national program. This is accomplished through ongoing monitoring of provider submissions to the state office and through formal Program monitoring reviews. Regular monitoring enables the state office to provide technical assistance as needed to accomplish Program objectives.

B. Internal Quality Assurance

TDH Quality Assurance Monitoring Division is responsible for conducting reviews of all BCCCP providers. These reviews occur during scheduled on-site visits with the state and provider staff. On-site visits are an important opportunity for both state office staff and providers to exchange and document ideas as well as discuss unresolved problems and issues. Following are the policies regarding program reviews for BCCCP providers:

TDH Monitoring of Contractors/Providers Policy

Contractors/providers shall provide funded services in accordance with the most recent TDH and applicable standards (Quality Care: Client Services Standards for Public Health and Community Clinics, Family Planning, Maternity, Child Health, etc.) and nationally recognized guidelines and standards of care. Subcontractors will also be monitored by TDH. (See Appendix A.)

On-site monitoring visits will be conducted to contractors/providers by a review team that consists of TDH Central Office Quality Assurance Monitoring Division and respective TDH Regional staff. At times, Central Office program staff may assist with the reviews. Every effort will be made to assist contractors/providers with technical assistance/training when problem areas are identified.

Purpose:

The purpose of on-site monitoring visits is to evaluate the contractor's/provider's compliance with applicable TDH and Program standards, policies, rules and requirements of the programs.

Scope of on-site monitoring visits:

On-site monitoring visits include the following activities:

1. Entrance Conference. This activity begins the review by allowing the contractor/provider staff an opportunity to provide information regarding the agency and services provided to the review team. It includes reviewing the agenda with the contractor/provider. The Director Administrator or Executive Director, the Medical Director, the Director of Nurses or Clinic Manager, Case Management Coordinator, and other applicable staff should be in attendance.

2. Review components:

   a. Administrative review to include:

      - $ Agency policies to include personnel, confidentiality, grievance, etc.
      - $ Client eligibility screening and determination as required by program
      - $ Review of billing for services
      - $ Record maintenance systems and policies as applicable
      - $ Fiscal/ food delivery system (WIC contractors only)

   b. Clinical review to include:

      - $ Quality Assurance Plan and documentation of activities
      - $ Observation of client/staff interactions (from start to the end of visit)
      - $ Review of clinical protocols, policies and standing delegation orders as appropriate
      - $ Random record reviews for each program reviewed
      - $ Community education plan and documentation of activities as applicable
      - $ Referral and follow-up system review
      - $ Triage system review, as applicable
      - $ Credentialing process

c. Facility review to include:

- $ Compliance with ADA requirements
- $ Required signage (No Smoking, Civil Rights, will not deny sign, clinic hours, evacuation, clinic identification sign)
- $ Properly equipped for services, etc., as applicable

4. Pharmacy review will include an evaluation of compliance with Class D Pharmacy Regulations as applicable

5. Population based Services (applicable to Part B Contractors only) review to include:

- $ Documentation of activities/participation
- $ Documentation of staff time spent on these services e.g. timesheets, etc.

3. Client interviews will be conducted randomly by review staff.

Contractor/provider screening/eligibility determination systems and individual client screening eligibility determination files will be monitored by TDH during an on-site quality assurance review. Some of the above components may not apply to case management providers.

3. Exit Conference. This conference is directed by the team leader and ends the review. The review team presents the positive findings and the areas that need improvement that were identified during the review. Even though the team tries to present all findings, in the interest of time, a summary is presented that identifies the major areas. Not all team members will speak even though everyone has participated in the review. However, prior to this activity the review team meets to organize the findings and identify the speakers. The team leader will begin the exit conference and will end the exit conference. Staff from the contractor/provider that should attend are identified above in the entrance conference section.

4. Review Team. The on-site monitoring visits will be conducted by a team of administrative, clinical and case management staff, as applicable, from Central Office and from the respective TDH Region. The size of the review team and number of days for the review will depend on the number of contractor/provider sites that provide the services. The review team will always have an identified team leader who will oversee the review. The team leader will be identified on the agenda that is sent to the contractor/provider prior to the visit.

Desk Reviews for MCM/TCM Providers

Some MCM/TCM reviews will be conducted through desk reviews. The following procedures will be utilized when a review is designated as a desk review.

Notification of review: Providers will be contacted by phone to schedule the abbreviated desk review. Information regarding services and systems will be obtained during this contact. Once a provider is notified of the review, the provider must submit to the Quality Assurance Monitoring Division a list of the clients being served by case manager. This list can be faxed. The list will be utilized to identify records that will need to be sent to the Quality Assurance Monitoring Division prior to the review. Records will be marked for the agency to submit the copies to the Quality Assurance Monitoring Division two days prior to the review. A copy of the provider's QA Plan will also be requested for submission two days prior to the review.

Entrance Conference will be conducted through a conference call. Staff who will be on the conference call will be decided with the scheduling of the visit. If it is an MCM review, the central office program representative will be responsible for initiating the conference call. If it is a TCM review, the QA Case Management Consultant will initiate the conference call. The call will be made to the provider as well as to the respective regional staff who will be involved in the review. Please refer to the policy *TDH Monitoring of Contractors/Providers* for information that should be covered during the Entrance Conference.

The visit will consist of observation of case managers on home visits (different case managers) or clinic visits as well as client interviews by the review team members. Observations will be conducted by regional staff. Credentialing of staff will be conducted and documentation of QA activities will be reviewed. Records will be reviewed during the visit (different records from those requested prior to the visit) and a billing review will be conducted. Records will be requested by regional staff at the time of the visit. Feedback will be provided to the provider at the completion of the on-site visit.

Exit Conference will be conducted through a conference call. Staff from the agency as well as central office staff and regional staff will participate. The Central Office MCM program staff or the QA Case Management consultant will coordinate the conference call for the exit. During this conference call, the findings of the record reviews conducted both as a desk review and those conducted at the site as well as the other findings will be covered. Provider staff may at this time ask questions. This conference completes the review.

The Report will be sent to the agency within 4-6 weeks after the review. Please refer to the Contractors/Providers Report policy for the additional information.

Scheduling of Contractor Visits Policy

On-Site Monitoring visits will be scheduled with the contractor/provider through a phone contact by a member of the Quality Assurance Monitoring Division, at least one month in advance of the visit. The contractor/provider may be contacted weeks prior to the scheduling to obtain a copy of the schedule of clinic services or information on other services. The agency must submit the most current schedule of services. Schedule must not be altered for the scheduled monitoring visit. Services must not be canceled for the site visit. The review will contain an observational component. The purpose of the observational component conducted during the visit is to observe services that agency staff provide as they are routinely provided.

A confirmation letter/memo will be sent to the agency prior to the visit. It is sent to the Director, Administrator, Medical Director or the contact person identified by the contractor/provider (please assure that TDH has the most current contact). The correspondence will be accompanied by an agenda outlining the activities of the review, an explanation of the Entrance and Exit conferences as well as the Quality Assurance Mission and Philosophy statement. Applicable and current Quality Assurance review tools and instructions to the tools will also be sent prior to the visit. The number of tools that will be sent depends on the number of programs that will be reviewed. All agencies will receive the Core Tool, which contains all the required elements of all TDH contractors.

The Quality Assurance Monitoring Division is attempting to coordinate visits with other programs outside the Deputyship to conduct more comprehensive visits. At times other programs will accompany the team for the visit. However, the program should notify the contractor/provider of their visit if not communicated by the Quality Assurance Monitoring Division.

Postponement or Rescheduling of Visits Policy

In order that TDH will have the opportunity to visit all contractors/providers, a contractor/provider may request an on-site monitoring visit be postponed or rescheduled only if one of the following situations occurs:

- $ a natural disaster or any other unforeseen situation or event occurs that completely or substantially disrupts the operations or services;
- $ the contractor has temporarily stopped providing services due to loss of staff (This condition applies only during the acute event of staff loss. Continued disruption of services will be regarded as an indication of need for technical assistance and/or review.)
- $ agency is moving to another facility during the review

$ provider who becomes inactive

TDH reserves the right to conduct an on-site monitoring visit under these conditions if the agency continues to provide client services.

If none of the reasons identified above exist for a contractor/provider, site visits will be scheduled in order that TDH is able to visit all of its contractors/providers.

Contractor/Provider Reports Policy

Draft Report:

After a site monitoring visit, a "draft" report will be sent to the contractor and/or provider. The report is sent four to six weeks after the visit. The "draft" is the preliminary report that is sent to the contractor/provider identifying the findings of the review. The contractor and/or provider will develop the corrective actions based on this report. The "draft" report also allows the agency to review and request correction of any areas that may have been incorrectly documented from information provided by the agency to the review team during the entrance conference. Any findings that were observed or reviewed (e.g. records, policies, etc.) will not be changed. The report consists of several parts. These include:

$ Cover letter/memo - which provides the instructions to the agency regarding the response as well as the report;
$ Executive Summary - provides a summary of the agency, visit, findings and recommendations. It is a summary of all the tools that are also part of the report;
$ Core Tool - contains all the minimum requirements of all TDH contractors. This tool is based on the Quality Care: Client Services Standards for Public Health and Community Clinics (not applicable to case management providers);
$ Program Tools - these contain the requirements of the program. The tools that will be sent to the agency will depend on the types of funding or services being reviewed.

The report will contain answers marked with a check-mark (✓). If a component is marked in the "yes" column, this means that this component was in compliance with the standard, rule, policy or requirement. If the component is marked in the "no" column, it means the component was not in compliance. A component may be marked in the "yes" and "no" columns, meaning that part of that component was in compliance while another was not. This is especially true in the case of the review of multiple clinic sites, observations and in the review of records. This may indicate that some of the records, observations or sites were in compliance with that particular component, but others

were not. If a component is not applicable, it will be marked in the "N/A" column or if a component is not required, it will be marked in the "N/R" column. When an item is marked "no" the comment section will identify the reason the item was not in compliance or it will identify a recommendation

regarding the item that was not in compliance. If a component is identified with a "yes" and a "no", the comment section will identify how the component was not in compliance. At times a statement will be added to the comment section when the component has been marked with a "yes". Usually these comments are made to identify a good system. At other times, even though the component is in compliance, a recommendation may be made as to other ways to enhance this area or make other improvement.

Response to the Report:

The contractor/provider is required to respond in writing to the "Draft" On-Site Evaluation Report. The response must identify corrective actions to all areas in the report that are marked with a "no", to include the "yes/no" answers. The response is due to the Quality Assurance Monitoring Division addressed to the Division Director within six weeks from the date on the letter or memo. A copy of this response should be submitted to the respective regional director. If for any reason, the contractor/provider is not able to respond within the allotted time, it is the responsibility of the contractor/provider to contact the Quality Assurance Monitoring Division Director to request an extension of the deadline. If a contractor/provider does not respond within the allotted time and a request for an extension is not received by the Quality Assurance Monitoring Division Director, a letter will be sent requesting a response in two weeks. If a response is not received within this time period, the contractor/provider may be placed on accelerated monitoring for a period of three months to assure that corrections are being made.

Final Report:

Once the agency has responded to the "draft" report and the response with corrective actions has been reviewed and accepted, a "final" report will be sent to the contractor/provider. The report will be exactly like the "draft" report unless a change was made for any reason. If changes are made, these will be identified in the cover letter. The "final" letter/memo will indicate to the agency if a follow-up visit will be made and the time period in which it will occur.

Follow-Up Visit Policy

Follow-up visits to a contractor or provider will be made when sufficient findings are identified during a visit that warrant a re-evaluation to assure corrections have been implemented. Follow-up visits are usually scheduled within six months of the initial visit unless otherwise specified. The contractor will be notified of the follow-up visit in the "final" letter/memo that is submitted with the "final" report.

The visit will be scheduled and conducted by the respective Public Health Region staff, program staff or QA Monitoring Division staff. The purpose of the visit is to evaluate implementation of the corrective actions submitted by the contractor/provider and to assure compliance with the standards, rule, and/or program requirements. The visit will review those areas that were not in compliance during the initial review. However, we reserve the right to re-evaluate areas that were found to be in compliance during the initial review if the review team deems it necessary.

The follow-up visit will include an Entrance and Exit Conference. The agency must not alter their schedules for the review nor should they cancel services. The follow-up visit must include observations of services and therefore, the contractor/provider should assure that review staff will be able to observe services on the dates identified.

Additional follow-up visits may be required if the agency has made progress in partially correcting the findings but all necessary corrections have not been completed. The additional follow-up visits will be conducted to allow the contractor/provider time to make the remaining corrections and ensure complete implementation of corrective actions. After each follow-up visit, a report will be sent to the contractor/provider. A written response is not required to be sent. The report will be accompanied by a letter/memo that will indicate to the contractor/provider if any additional visits are needed r if all has satisfactorily been corrected.

If it is identified during a follow-up visit that the agency has failed to implement the corrective actions submitted to the Central Office, Quality Assurance Division, the agency may be placed on Accelerated Monitoring (see Sanctions policy) or if the findings have become of a grave nature, the agency may progress to Probationary status.

Contractor Sanctions Policy

Unsatisfactory review findings may result in TDH sanctions being imposed. Sanctions vary in severity and may be of a progressive nature. A contractor/provider may be sanctioned at any level as may be indicated by the severity of the findings. The sanctions include:

$ Accelerated Monitoring

- $ Probation
- $ Suspension of funds
- $ Cancellation of a contract or termination as a provider
- $ Non-renewal of a contract
- $ Other actions as deemed appropriate under conditions of the contract, program rules or policy

Technical assistance may be obtained by the contractor during the sanctioning process. Quality assurance review findings will be utilized in decision making regarding future funding.

Accelerated Monitoring is the lowest form of sanctioning and is for an identified period of time. During this period of time the contractor/provider is closely monitored to evaluate implementation of corrective actions as required. At the end of the sanctioning period, a decision is made regarding any progressive sanctions or if the contractor/provider will move out of the sanctioning status. Progressive sanctions such as probation also are for a specified period of time. If after the progressive sanctioning period, the contractor/provider has not satisfactorily made the required corrections, the Quality Assurance Monitoring Division will refer the contractor/provider to the program for further action.

2. Internal Quality Assurance Policy

All contractors/providers must have an implemented internal Quality Assurance Program. The goal is that the agency have a system to assure quality services to the clients they serve. The contractor/provider should assure compliance with relevant standards, guidelines, rules as well as applicable Federal and State laws.

The contractor's internal Quality Assurance Program must consist of the following components:

(1) The agency's Mission and Philosophy statement that includes quality assurance.

(2) A Quality Assurance Committee

a. Must include at a minimum:

- $ Executive Director, CEO, or Agency Director
- $ Medical Director
- $ Director of Nurses or Clinical Manager
- $ Medical records person or clerical representative.

b. Must have the following areas identified:

- $ Purpose of committee
- $ Scope of duties of quality assurance committee must be defined
- $ Responsibilities of each member of the committee
- $ Frequency of meetings
- $ Procedures to be utilized to identify findings, identify corrective actions and follow-up to assure corrections are made.

c. Must identify other members of the agency that will be involved in quality assurance activities. It must identify their responsibilities and how they will relate to the committee.

3. Areas to be reviewed and the frequency of reviews must be identified. Areas that should be reviewed to assure a comprehensive quality assurance plan are:

a. Administrative

- $ Updated agency, record, personnel, policies, etc.
- $ Current job descriptions
- $ Current employee performance evaluations
- $ Current Organizational Chart

b. Facility

- $ Compliance with American with Disabilities Act requirements
- $ Fire and Safety
- $ Fire extinguishers

c. Pharmacy

- $ Assurance of documentation of required activities under the class of pharmacy
- $ Current formulary
- $ Inspections and training according to regulations

d. Clinical

- $ Credentialing
- $ Updated protocols and Standing Delegation Orders as appropriate
- $ Observation of client/staff interactions
- $ Record Reviews

4. Standardized tools must be developed to conduct quality assurance activities:

- $ To assure standardization
- $ To document findings

5. Time periods and identification of sampling must be identified for activities:

    - $ Record reviews quarterly. Consider 10% or a minimum number of records and quarterly (the sample needs to be large enough to identify problems if there are any)
    - $ Observation at least annually

6. Individuals who will carry out activities e.g. record reviews and observations should be identified if they are different from the quality assurance committee.

7. A process must be clearly identified as to how many quality assurance findings will be communicated to the quality assurance committee.

8. A process must be developed to assure corrective actions are identified and by whom.

9. A follow-up process to assure corrective actions must be identified:

    - $ A process should be developed to address corrections that are not made.

10. A process must be identified by which staff development is provided based on quality assurance findings.

11. A process must be identified to monitor adverse outcomes:

    - $ Actions to be taken
    - $ System of tracking
    - $ Documentation
    - $ Reported to whom

12. A process must be identified to identify and monitor outcome measures:

    - $ How will the outcomes be identified
    - $ How will they be tracked
    - $ Frequency by which they will be tracked
    - $ Reporting of outcomes
    - $ Changes that need to be made to the identified outcomes
    - $ Client satisfaction

TDH Monitoring of Contractors/Providers Policy *continued*

Contractors who subcontract with other agencies to provide services, must have a process to evaluate the services provided by the subcontractor to ensure compliance with standards and requirements and must document these activities. This must be clearly stated in the subcontract. Texas Department of Health (TDH) staff who conduct reviews of the contractor need to be able to visit the subcontractors to review the services provided. Therefore arrangements must be made by the contractor to allow for this. Case management providers cannot subcontract.

C. Mammography and Cytology

The BCCCP has a responsibility for developing and providing quality assurance procedures and protocols for mammography and cytology screening for state activities. Each BCCCP provider must negotiate and monitor its contracts with local mammography providers to assure full compliance with federal Centers for Disease Control and Prevention (CDC)/BCCCP guidelines as well as federal quality assurance requirements. This includes verifying current certification by federal and state regulatory agencies. Each BCCCP provider must assure mammography providers reimbursed under the Program meet federal quality assurance requirements outlined in the Federal Mammography Quality Reauthorization Act (MQRA). The TDH Bureau of Radiation control (BRC) can be contacted directly to obtain results of BRC inspections of mammography facilities participating in the BCCCP. BRC generally will notify the BCCCP if a mammography facility is in "escalated enforcement" or "cease and desist" status. **The BCCCP will not reimburse for services provided by a mammography subcontractor with "escalated enforcement" status or "cease and desist" status.**

The use of a common reporting system for documenting and evaluating mammogram results is a critical concern of the state office and CDC. The MQRA establishes common reporting classifications for mammogram results. BCCCP requires use of these final assessment classifications for reporting mammogram results. **The BCCCP will only reimburse a provider for a mammogram that was reported using the approved MQRA overall assessment of findings classifications.** Providers are responsible for monitoring and assuring each mammogram report is in compliance.

The BCCCP is also responsible for assuring that all cervical cytology conducted under the Program meets requirements established by CDC. The Bethesda System for Reporting Cervical and Vaginal Diagnoses is required for reporting all cytology results under the BCCCP.

D. Professional Education and Clinical Protocols

The BCCCP dedicates substantial resources for professional education activities each year. The BCCCP provides a variety of professional education opportunities both at local sites and at well recognized training programs such as M.D. Anderson Cancer Center in Houston. Specialized training opportunities are also available upon request.

Prior to the start-up of a new provider, an orientation in-service for all provider staff involved in the operations of the BCCCP will be conducted by state office staff. The in-service will provide information on BCCCP standards and policies, performance indicators, data and billing requirements. BCCCP training modules have been developed for the orientation of new staff for existing providers. Training for existing providers can be provided by state office when deemed necessary by state office staff and the provider.

The Program develops and updates clinical protocols for screening and follow-up of women for breast and cervical cancer. These protocols are included in the Reference section of this manual. The protocols must be approved by the Advisory Committee of the Program and also by the CDC.

E. Grants Management Reviews

The TDH Grants Management Division conducts annual monitoring reviews of financial and administrative operations of each BCCCP provider. Monitoring reports from Grants Management are routinely shared with BCCCP staff to use in performance monitoring. In preparing for monitoring by the Grants Management Division, BCCCP providers should review the TDH General Provisions for Contracts or refer questions to the Grants Management Division, Program Monitoring Section.

II. REIMBURSEMENT FOR CLIENT SERVICES

The BCCCP reimburses for each allowable service provided. A service usually consists of several procedures such as screening mammograms, diagnostic mammograms, fine needle aspiration, office visits, colposcopy, colposcopy with biopsy, and pathology. Providers may request up to ten percent of the total amount requested for clinical procedures to recover administrative costs associated with providing Program services. **The total reimbursement for administrative cost must be less than or equal to 10 percent of the request for funding for clinical procedures.**

The federal law requires that <u>at least</u> 60 percent of a state's grant awarded be dedicated to direct clinical services for women. To implement the program each year, CDC identifies the specific client services and procedures that can be reimbursed with the federal funding.

By federal law, payments for clinical services provided under the BCCCP must be based on Medicare rates. Each year the BCCCP State office develops reimbursement rates for the BCCCP and must obtain approval from CDC for these rates. Generally, the local or an average of Texas Medicare rates for the approved procedures are used to determine the reimbursement rate (based on the Medicare Fee Schedule Database).

Budgets are negotiated with each provider at least annually, based on provider costs for the services provided and the provider's history in expending awarded funds. Only providers that are in compliance with all Program requirements and are satisfactorily expending funds are eligible for supplemental funds when these become available.

Providers are required to provide matching (non-federal cash or services that will be reimbursed by the program provider) contributions along with the services reimbursed by BCCCP. For example, many BCCCP providers assume costs associated with outreach campaigns and contribute significant staff time to a variety of BCCCP-related activities.

III. PROGRAM COMMUNICATIONS

The BCCCP uses a variety of methods to communicate with providers regarding regular and new Program activities and requirements. Quarterly, the *Commitment* newsletter is mailed to all providers to report on program issues or other required activities. Each provider must assure local Program staff receive these updates and interpretation regarding regular program operations. Local staff should contact the state office if they do not receive a new issue of the *Commitment* on a quarterly basis.

Several times a year, the BCCCP will publish a *Clinical Update* on pertinent breast and cervical cancer control issues. This is inserted in the *Commitment*. Questions from providers and suggestions on articles or topics for the *Commitment* are welcome and should be directed to the editor at 800-452-1955.

There are a variety of materials available through the Program for client education purposes. You may also use the Client Education Materials Order Form (enclosed) to order additional supplies or materials.

IV. OTHER TDH RESPONSIBILITIES

BCCCP staff are responsible for establishing program standards in accordance with Public Law 105-340 and with CDC requirements and guidelines. BCCCP staff are also responsible for coordination within TDH to provide a central point of contact with contractors regarding the program, contractual, and financial requirements.

The following are some of the other major responsibilities of the BCCCP:

$ developing guidelines and protocols for client services, tracking, follow-up, and case

management interventions;

- $ convening performing agencies for regular information-sharing and training;
- $ providing technical assistance to providers as needed;
- $ compiling and disseminating a Manual of Operations (MOO) and reviewing/revising it as needed;
- $ developing program indicators for assessing performance and routinely providing agencies feedback on their performance;
- $ communicating provider concerns and questions related to Program operations to CDC; and
- $ seeking and promoting additional support to enable providers to expand operations as needed.

APPENDIX A

QUALITY CARE: CLIENT SERVICE STANDARDS FOR PUBLIC HEALTH AND COMMUNITY CLINICS